

**REMARKS**

Claims 1-23 are pending. Claim 1 is the sole independent claim under consideration.

**Priority Award**

In the action mailed July 5, 2006, the application was awarded a priority date of July 11, 2003. This was based an alleged failure to provide written description that encompassed the detection of cells beyond cells having a proliferative disorder (i.e., the identification of a "rare event") in any of the priority documents.

Applicant respectfully disagrees with priority award and submits that the present application is entitled to the benefit of earlier filing dates.

As a threshold matter, 35 U.S.C. § 120 states that the benefit of earlier filing date in the United States is available when, *inter alia*,

"an invention [is] disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States..." (emphasis added)

However, the present Office action has attempted to assign a single priority date to all of the claims based on the subject matter recited in claim 1. This is manifestly improper, since *it is the scope of the claimed subject matter that determines*

the right of priority and the present claims do not all have the same scope. For example, claim 3 recites that a "sub-population is enriched for carcinoma cells." Applicant respectfully submits that even if, *arguendo*, the genus recited in claim 1 were not fully disclosed, the detection of carcinoma cells is fully disclosed by the description of the enrichment of cells having a proliferative disorder. Claim 3 is thus clearly entitled to the benefit of earlier filing dates.

Moreover, it is well-established that the written description requirement of 35 U.S.C. § 112, first paragraph requires that a patent specification describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., M.P.E.P. § 2163.I (citing Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).*

In the present situation, Applicant has clearly contemplated the use of the disclosed systems and techniques in contexts outside the detection of cells having a proliferative disorder before July 11, 2003. For example, a description of the application of the claimed scanning and imaging to rare event detection is found, *e.g.*, at page 9, line 8-11 and page 22, line 7-9 of U.S. Provisional Application Serial No. 60/129,384 (filed April 13, 1999). Similar description is found at page 9, line 11-13 and page 22, line 15-17 of U.S.

Application Serial No. 09/344,308 (filed June 24, 1999).

Indeed, the detection of cells having a proliferative disorder is identified as one example of rare event detection at page 8, line 4-14 of U.S. Application Serial No. 09/619,033 (filed July 19, 2000). This disclosure is fully consonant with the discussion of cells having proliferative disorders being too few in number to provide a detectable signal found at page 1, second paragraph of U.S. Provisional Application Serial No. 60/144,529 (filed July 19, 1999).

Indeed, at least some of the specific examples of rare event detection identified in the Office action as allegedly not being described in the priority applications are, in fact described in those applications. For example, page 12, line 6-15 of U.S. Application Serial No. 09/344,308 (filed June 24, 1999) specifically describes detection of a fetal cell in maternal blood. Comparable disclosure is found in page 11, line 26 - page 12, line 8 of U.S. Provisional Application Serial No. 60/129,384 (filed April 13, 1999).

As another example, the discussion of the differential staining of muscle fibers and red blood cells by H/E at page 13, line 5-8 of U.S. Application Serial No. 09/344,308 (filed June

24, 1999) can be used for the detection of myocardial cells in blood. Comparable disclosure is found in page 12, line 24-27 of U.S. Provisional Application Serial No. 60/129,384 (filed April 13, 1999).

Applicant also submits that, even if *arguendo* the priority applications did not expressly describe the detection of rare events, a description of the detection of cells having a proliferative disorder suffices to support the generic claims directed to the detection of rare events. In this regard, possession of a genus can be shown through sufficient description of a representative number of species. See, e.g., M.P.E.P. § 2163.II.3(a)ii. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. See, e.g., M.P.E.P. § 2163.II.3(a)ii.

Applicant respectfully submits that the claimed detection of other rare events shares sufficient common attributes and features with the detection of cells having a proliferative disorder so that the disclosure requirements of 35 U.S.C. § 112, first paragraph are satisfied for the generic claims. In this regard, claim 1 presently relates to contacting the source with a binding agent specific for a cell specific marker associated

with a rare event and expressed by at least some of the cells and separating cells bound by the binding agent from the source thereby obtaining a sub-population of cells enriched for the cell specific marker associated with the rare event. The binding agent is bound to a magnetic bead. The binding agent binds to cells in the source expressing the cell specific marker.

There is no reason to believe that the claimed contacting and separating are dramatically different when cells having a proliferative disorder are detected or when cells with other rare events are detected. For example, the specification makes it clear that mono- and polyclonal antibodies have been developed for a number of antigens, and there is no reason to believe that such antibodies cannot be used in the claimed contacting and separating.

Accordingly, Applicant respectfully submits that claim 1 is entitled to a priority date before July 11, 2003. Also, the dependent claims are entitled to priority dates before July 11, 2003, based not only on their dependence from claim 1 but also on the scope of the subject matter claimed therein.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claim 15 was rejected under 35 U.S.C. § 112, first paragraph. Claim 15 has been amended to address the Examiner's concerns and new claim 19 has been added.

**Rejections under 35 U.S.C. § 102**

Claims 1-4, 6-13, 17, and 18 were rejected under 35 U.S.C. §§ 102(a), (e) as anticipated by PCT Publication No. WO 03/035895 to Immunivest (hereinafter "Immunivest I").

35 U.S.C. § 102 states that a person is entitled to a patent unless:

"(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,..."

(e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language..."

As discussed above, claim 1 is fully entitled to the priority date before July 11, 2003. Indeed, it appears that claim 1 is entitled to a priority date of at least one of April 13, 1999 or July 19, 1999. Since the earliest possible priority date for Immunivest I is October 26, 2001, Applicant respectfully submits that Immunivest I is not prior art under either 35 U.S.C. §§ 102(a) or (e).

Accordingly, Applicant respectfully requests that the rejections of claim 1 and the claims dependent therefrom be withdrawn.

Claims 1-4, 6-14, and 16-18 were rejected under 35 U.S.C. §§ 102(a), (e) as anticipated by U.S. Patent Publication No. 2003/0017514 to Pachmann et al. (hereinafter "Pachmann").

As discussed above, claim 1 is fully entitled to the priority date before July 11, 2003. Indeed, it appears that claim 1 is entitled to a priority date of at least one of April 13, 1999 or July 19, 1999. Since the earliest possible priority date for Pachmann is June 2, 2001, Applicant respectfully submits that Pachmann is not prior art under either 35 U.S.C. §§ 102(a) or (e).

Accordingly, Applicant respectfully requests that the rejections of claim 1 and the claims dependent therefrom be withdrawn.

Claims 1-4, 6-13, and 17-18 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Publication No. WO 02/06790 to Immunivest (hereinafter "Immunivest II").

As discussed above, claim 1 is fully entitled to the priority date before July 11, 2003. Indeed, it appears that claim 1 is entitled to a priority date of at least one of April 13, 1999 or July 19, 1999. Since the earliest possible priority date for Immunivest II is July 14, 2000, Applicant respectfully submits that Immunivest II is not prior art under 35 U.S.C. § 102(b).

Accordingly, Applicant respectfully requests that the rejections of claim 1 and the claims dependent therefrom be withdrawn.

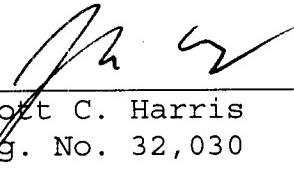
Rejections under 35 U.S.C. § 103(a)

Claims 1-18 were rejected under 35 U.S.C. § 103(a) as obvious over Immunivest I, Pachmann, and Immunivest II in combination with various other references.

As discussed above, none of Immunivest I, Pachmann, and Immunivest II are prior art to the present application. Accordingly, the rejections under 35 U.S.C. § 103(a) are improper and applicant asks that they be withdrawn.

Applicant asks that all claims be allowed. Please apply the \$50 fee for the excess claim and any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

  
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